ABBOTT LABORATORIES

**Medical Products Group**

April Veoukas
Medical Products Group
D-3MQC, AP6C-1
Telephone: (847) 937-8197

100 Abbott Park Road
Abbott Park, Illinois 60064-6091
Facsimile: (847) 938-4422
E-mail: april.veoukas@abbott.com

February 23, 2005

Division of Dockets Management (HFA –305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20857

**RE:** *MedWatch: Food and Drug Administration Medical Products Reporting Program [Docket 2004N-0535]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA's information collection activities pertaining to "MedWatch: Food and Drug Administration Medical Products Reporting Program" published in the Federal Register on December 27, 2004 at 69 FR 77256.

Our comments pertain to the proposed modifications to the forms. We recommend the agency allow continued use of the existing forms for a period of six months from issuance of the final proposed forms, so manufacturers that submit computer-generated MedWatch forms will have time to modify and validate existing computer software systems to comply with the new requirements. An interim period of six months is consistent with the previous allowance granted by FDA when it last modified the forms in 2003.[1]

In response to the agency's request for comments on the accuracy of FDA's estimate of the burden of the proposed collection information, we note the agency has not captured the hours required to modify and validate the proposed changes to the MedWatch form. Based on the previous modifications, 50-60 hours are needed to modify and validate the changes to the form per computerized system.

[1] *See* Federal Register Notice, Docket 2003N-0016, published October 10, 2003, which states, "as requested by the agency, in addition to the approval of the revised forms, the existing forms are approved for continued use for the next six months to allow for the industry to make necessary changes to their computerized systems" at 68 Federal Register 58691.

ABBOTT LABORATORIES

Thank you for the opportunity to provide these comments. Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

April Veoukas

April Veoukas, J.D.
Associate Director, Regulatory Affairs
Medical Products Group
Abbott Laboratories